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DATA EVALUATION RECORD

PROHEXADIONE CALCIUM TECHNICAL
(BX-112)

Study Type: §81-5; Primary Dermal Irritation

Work Assignment No. 1-02-25A (MRID 44457746)

Prepared for
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U.S. Environmental Protection Agency
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Disclaimer

This Data Evaluation Record may have been altered by the Health Effects Division subsequent to signing by Dynamac Corporation personnel.

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For A/K Murphy 8/22/99

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DATA EVALUATION RECORD

STUDY TYPE: Primary Dermal Irritation - Rabbit
OPPTS Number: 870.2500 OPP Guideline Number: §81-5

DP BARCODE: D246707 SUBMISSION CODE: S543930
P.C. CODE: 112600 TOX. CHEM. NO.: None

TEST MATERIAL (PURITY): Prohexadione calcium technical (93.3% purity)

SYNONYMS: BX-112; calcium salt of 3,5-dioxo-4-propionylcyclohexane-1-carboxylic acid; KIM-112; KUH-833

CITATION: Jones, J. (1989) BX-112: primary dermal irritation test in the rabbit. Safepharm Laboratories Limited, Derby, U.K. Laboratory Project Number 131/94. September 12, 1989. MRID 44457746. Unpublished.

SPONSOR: BASF Corporation, P.O. Box 13528, Research Triangle Park, NC.

EXECUTIVE SUMMARY: In a primary dermal irritation study (MRID 44457746), six young adult New Zealand White rabbits were dermally exposed to 0.5 g of prohexadione calcium technical (93.3% purity) for 4 hours; the test substance was moistened with distilled water and applied to a single intact 6.25-cm^2 site/animal. Animals were observed for dermal irritation for up to 72 hours following patch removal, and irritation was scored by the Draize scale.

No dermal irritation was observed during the 72-hour observation period. In this study, **prohexadione calcium technical is not a dermal irritant**, and is classified as **TOXICITY CATEGORY IV** for primary dermal irritation.

This study is classified **acceptable (§81-5)** and satisfies guideline requirements for a primary dermal irritation study in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS:

1. Test Material: Prohexadione calcium technical (BX-112)
   Description: Off-white powder
   Lot/Batch #: G14-07
   Purity: 93.3%
   CAS #: 127277-53-6

2. Vehicle and/or positive control: Distilled water, 0.5 mL/application

3. Test animals: Species: Rabbit
   Strain: New Zealand White
   Age: Young adult (approximately 12-16 weeks)
   Weight: 2.56-3.05 kg (combined sexes)
   Source: David Percival Ltd., Moston, Sandbach, Cheshire, U.K.
   Acclimation period: ≥5 Days
   Diet: Rabbit Diet, Preston Farmers Limited, New Leake, Boston, Lincolnshire, U.K., ad libitum
   Water: Tap water, ad libitum
   Housing: One animal/cage in suspended metal cages
   Environmental conditions:
   Temperature: 16-24 °C
   Humidity: 56-70%
   Air changes: 15 air changes/hour
   Photoperiod: 12-hour light/dark cycle

B. STUDY DESIGN and METHODS:

1. In-life dates: August 1-4, 1989

2. Animal assignment and treatment: Fur from the dorsal trunk and flank areas of six young adult New Zealand White rabbits (five male and one female) was clipped approximately 24 hours prior to dermal administration with 0.5 g of prohexadione calcium technical. The test substance was moistened with distilled water and applied to a single intact application site/animal beneath a 6.25-cm^2 gauze patch. The patches were secured with Blenderm surgical adhesive tape, and the trunk of each animal was wrapped with a Tubigrip elasticated corset. Following a 4-hour exposure period, the coverings were removed, and the test sites were gently wiped with water-moistened cotton wool. The rabbits were observed for dermal irritation at approximately 1, 24, 48, and 72 hours following patch removal. Erythema and edema were scored separately using the Draize scale.

II. RESULTS AND DISCUSSION:

A. Clinical observations: No dermal irritation was observed during the 72-hour observation period. In this study, prohexadione calcium technical is not a dermal irritant.

B. Deficiencies: There were no deficiencies that affected the results of this study.